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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,472	12/26/2001	Jan Liska	64695	2987

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YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

[REDACTED] EXAMINER

GILPIN, CRYSTAL M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

3738

DATE MAILED: 04/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/025,472	LISKA ET AL.
	Examiner	Art Unit
	Crystal M Gilpin	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 4 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-10 and 29-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 11-14, it is unclear in the first line of the claim whether the “means for repair” or the “cardiac valve” comprise an anterior and posterior leaflet, etc.

Regarding claim 23, Applicant fails to disclose a “net-formed” structure, strip or band in the specification. Therefore, the language of claim 23 lacks antecedent basis. The Examiner has interpreted this language to mean that the stabilizing element has the shape of a net since “net-shaped” (Page 6, Line 5) is disclosed in the specification.

Claim 24 recites the limitation "each" in –intermediate section of *each* structure, strip or band-. There is insufficient antecedent basis for this limitation in the claim because a strip or band has not been disclosed in claim 20 or claim 13 on which claim 24 depends. Claim 24 is

further rejected as having insufficient antecedent basis in the specification because Applicant fails to disclose a strip or band that is “shaped in the form of a ring”. The Examiner has interpreted the claimed strip and band as referring to the stabilizing element.

Claim 25 recites the limitation “each” in –intermediate section of *each* structure, strip or band-. There is insufficient antecedent basis for this limitation in the claim because a strip or band has not been disclosed in claim 20 or claim 13 on which claim 25 depends. Claim 25 is further rejected as having insufficient antecedent basis in the specification because Applicant fails to disclose a strip or band that is “shaped in the form of a circular disc”. The Examiner has interpreted the claimed strip and band as referring to the stabilizing element.

Claim 26 is indefinite because of the words enclosed in parentheses. It is unclear whether the enclosed terms are positively required or not.

Claim 27 and 28 recite the limitation of “assessed” in –is *assessed* to the posterior mitral leaflet base-. It is unclear how the Applicant is using the word “assessed” in the context of the claim. The Examiner has interpreted the claims to mean that valve has a position at the posterior and anterior to the leaflet base, as disclosed in the specification (Page 6, Lines 11-13).

Claims 15-22 are rejected to as being dependent on claims 11-14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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2. Claims 11-25, 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Mortier et al. (USPN 6,332,893).

Regarding claim 11, Mortier et al. disclose a means for repair of a cardiac heart valve comprising an anterior and posterior leaflet (Fig. 2, Ref. # 16), which can protrude from the leaflet base (upon opening) and is arranged to modify or improve the cardiac valve by creating an improved chamber geometry (Column 1, Lines 47-49). Mortier et al. further teach of stabilizing elements (Fig. 4, Ref.# 24) that extend across the cardiac valve (Fig. 8) and have a first and second end (Column 1, Lines 55-56).

Regarding claim 12, it is inherent to implant the means for repair of a cardiac valve with a steerable applicator such as a catheter.

Regarding claims 12 and 14, the steerable applicator is not considered as part of the means for repair of the cardiac valve as set forth in the preamble of the claim. Rather, it appears to be part of a statement of intended use for delivering the stabilizing element, where the steerable applicator is not a positively required structure or means.

Regarding claims 14, 27 and 28, Mortier et al. discloses that the replacement could be for the mitral valve which is at the top of the left ventricle (Column 3, lines 8-9), and therefore it is inherent that the steerable applicator could be maneuvered through the left atrium in order to access the left ventricle. Regarding claims 27 and 28 it is further inherent that the mitral valve replacement would be positioned to the posterior and anterior of the natural mitral valve base.

Regarding claims 15 and 17, Mortier et al. disclose that the size of the annulus of the valve, comprising the distance between the anterior and posterior leaflets, could be changed using varying suture lengths, resulting in different lengths of tension members (Column 3, lines

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40-50). Mortier et al. further disclose that various changes in shape, size and arrangement of the parts of this invention is possible (Column 5, Lines 36-39), and that the tension members or stabilizing elements can be fixably or releasably attached to the basal anchor allowing for adjustment of the stabilizing elements. The varying of lengths of the stabilizing or tension members inherently allows for repair of prolaps.

Regarding claim 16, the tensions members support the functioning of the leaflets by altering the geometry of the heart in order to reduce stress.

Regarding claims 18, 19, 20, 21 and 22, Mortier et al. disclose that the tension members can be substantially rigid or substantially flexible, comprising a rod or a wire, and in Fig. 11, Ref.# 424 show that the tension member could comprise a strip or band.

Regarding claim 23, in Fig. 6 Mortier et al. disclose that the strips that comprise the tension members can be in the shape of a net.

Regarding claims 24 and 25, Mortier et al. discloses that the stabilizing element is comprised of the combination of the basal anchor (Fig. 4, Ref. # 22) and the tension members. This basal anchor comprises the intermediate structure of the stabilizing element and is shaped in the form of a ring or circular disc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mortier et al. (USPN 6,332,893) in view of Schreck (USPN 6,454,799).

Regarding claim 26, Mortier et al. discloses means for the repair of a cardiac valve, however they lack the teaching of a steerable applicator with sheath for the implantation of the means. Schreck teaches of a heart valve implantation method that includes a catheter (Fig. 16A, Ref. # 212) that is encased in an inserting device (guidance sheath, Fig. 16A, Ref.# 218) to allow for a minimally invasive procedure. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Mortier et al. to have a steerable applicator encased in a sheath to provide means for a minimally invasive heart valve implantation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
April 21, 2003


Paul B. Preble
Primary Examiner